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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,801	07/06/2001	Richard Eustis Fulton III	ARTM 1000-5US	6827

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EXAMINER
SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	21

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/900,801	FULTON ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003 and 29 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89,90,94-101,103,118-139,141-148,150 and 152-167* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89,90,94-101,103,118-139,141-148,150 and 152-167* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 89, 90, 94-100, 103 and 144-147 are rejected under 35 U.S.C. 102(e) as being anticipated by Corbitt, Jr. et al.

Corbitt, Jr. et al disclose a bioabsorbable breast implant and further disclose a bioabsorbable element in a pre-delivery state; the bioabsorbable element comprising a chemotherapeutic agent; the element is in a post-delivery state at the target site; the element is remotely visualizable within the surrounding soft tissue in the post-delivery state; the element comprises means for subsequently receiving a therapeutic agent; the receiving means comprises a radiation agent, a gene therapy agent, or a chemotherapy agent; a marker element in contact with the bioabsorbable element; the marker is a permanent or a temporary marker element; the bioabsorbable element is physically different in the post-delivery state from the pre-delivery state; taking tissue from a target site; selecting a remotely visualizable bioabsorbable element; positioning the element at the target site; the positioning step is carried out using an element that is at least partially radiopaque; the tissue taking step is carried out at a biopsy site; and the

positioning step is carried out using remote visualization. See Column 3, lines 15-31 and 54-60; and Column 4, lines 5-16 and 31-41.

Corbitt, Jr. et al explicitly disclose a bioabsorbable element with a radiopaque element or substance within the element for remote visualization, and thus, implicitly encompass locating the marker at a generally central location in the element. The disclosure in Column 4, lines 31-41 is broad enough to encompass locating the marker element centrally.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbitt, Jr. et al as applied to claim 94 above, and further in view of Foerster et al ('055).

Corbitt, Jr. et al, as discussed above, disclose a remotely visualizable bioabsorbable therapeutic implant, but fail to disclose the element being remotely visualizable by at least one of ultrasound and mammography.

Foerster et al disclose a device and method for marking and defining biopsy locations and further disclose the element being remotely visualizable by at least one of ultrasound and mammography. See Column 8, lines 65-67; Column 9, lines 1-4; and Column 13, lines 16-26 and 33-36.

Since both Corbitt, Jr. et al and Foerster et al disclose bioabsorbable elements placed at a biopsy site, it would have been obvious to one of ordinary skill in the art a the time the invention was made to modify the device of Corbitt, Jr. et al to include the use of ultrasound or mammography to locate the element, as per the teachings of Foerster et al, since it would provide a means for easily relocating the biopsy site at a later time if further treatment is necessary.

7. Claims 118-122, 125-131, 134-139, 143, 148, 150, 152-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbitt, Jr. et al in view of Foerster et al ('055).

Corbitt, Jr. et al, as discussed above, disclose a remotely visualizable bioabsorbable therapeutic implant and method for implanting the element and the bioresorbable body is polyglycolic acid; at least one bioresorbable body; and the marker is contained within the body (See Column 4, lines 5-16 and 31-41), but fail to disclose testing the removed tissue sample; if testing indicates a need to do so, relocating the target tissue by finding the element by palpation; the element being remotely visualizable by at least one of ultrasound and mammography; and the medical treating step comprises removal of tissue.

Foerster et al, as discussed above, disclose a device and method for marking and defining biopsy locations and further disclose testing the removed tissue sample; if testing indicates a need to do so, relocating the target tissue by finding the element by palpation; the element being remotely visualizable by at least one of ultrasound and mammography; and the medical treating step comprises removal of tissue. See Column

1, lines 19-23; Column 3, lines 26-33; Column 7, lines 24-26 and 41-65; Column 8, lines 62-67; Column 9, lines 1-4; and Column 13, lines 16-26 and 33-36.

Since both Corbitt, Jr. et al and Foerster et al disclose bioabsorbable elements placed at a biopsy site, it would have been obvious to one of ordinary skill in the art a the time the invention was made to modify the device and method of Corbitt, Jr. et al to include the use of ultrasound or mammography to locate the element after the sample was tested, as per the teachings of Foerster et al, since it would provide a means for easily relocating the biopsy site at a later time if further treatment is necessary. It also would have been obvious to relocate the biopsy site through the inflammation at the site caused by the absorbable element, since it is well known that a foreign body placed inside the body causes the body to react to the foreign body, even if the foreign body is composed of biocompatible material, thus causing inflammation. It would have been obvious to one of ordinary skill in the art to recognize that either of the implantable elements of Corbitt, Jr. et al or Foerster et al would have a hardness of at least 1.5 times the surrounding tissue, since a bioabsorbable foreign body would inherently be harder than the surrounding tissue. Corbitt, Jr. et al explicitly disclose a bioabsorbable element with a radiopaque element or substance within the element for remote visualization, and thus, implicitly encompass locating the marker at a generally central location in the element. The disclosure in Column 4, lines 31-41 is broad enough to encompass locating the marker element centrally. It also would have been obvious to one of ordinary skill in the art to relocate the biopsy site prior to medically treating the area, since the oncologist would obviously need to find the site to provide the necessary

medical treatment in order to prevent the cancer from regrowing or spreading throughout the body.

8. Claims 123, 124, 132, 133, 141 and 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbitt, Jr. et al and Foerster et al ('055) as applied to claims 118, 127 and 136 above, and further in view of Unger et al.

Corbitt, Jr. et al and Foerster et al, as discussed above, disclose bioabsorbable elements placed at a biopsy site, but fail to disclose preventing blood from contacting the element until the element is at the target site; and the preventing step is carried out using a hemostatic bioabsorbable element having a non-hemostatic biodegradable outer layer.

Unger et al disclose a means for ultrasound imaging a target site, and further disclose preventing blood from contacting the element until the element is at the target site; and the preventing step is carried out using a bioabsorbable element having a non-hemostatic biodegradable outer layer. See Column 6, lines 62-67; Column 7, lines 1-4 and 7-38; Column 21, lines 63-67; Column 22, lines 1-3 and line 40 and lines 47-48; Column 73, lines 35-40.

Since Corbitt, Jr. et al, Foerster et al and Unger et al disclose bioabsorbable elements, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Corbitt, Jr. et al and Foerster et al to include a biodegradable outer layer that protests the element, as per the teachings of Unger et al, since it would provide a means of preventing the element from deploying to the post-delivery state before the element has been placed at the biopsy site.

Response to Arguments

9. Applicant's arguments filed October 22, 2003 have been fully considered but they are not persuasive. The current application claims priority to June 22, 1998 to provisional application 60/090,243, filed by Dubrul. Upon review by the Examiner regarding the subject matter disclosed in the above provisional application, it was found the claimed subject matter is not supported by the disclosure of 60/090,243. The disclosure states the use of a biopsy marker that has a pre- and post-delivery state as well as having the ability to absorb an injected fluid. The disclosure does not state the injected fluid as a "therapeutic agent" or "chemotherapy agent" as claimed in the current claims of the application. Therefore priority cannot extend to the filing date of 60/090,243. The provisional application that was filed by Dubrul that supports the use of a "chemotherapeutic agent" or a "therapeutic agent" with the marker is 60/117,421 filed on January 27, 1999.

Corbitt, Jr. et al filed a provisional application on June 30, 1998, 60/091,306, that discloses the use of a "therapeutic agent" as well as a "chemotherapy agent" in the device that is placed in the region of removed breast tissue.

Therefore, since the filing of 60/091,306 (June 30, 1998) predates the filing of 60/117,421 (January 27, 1999), the patent to Corbitt, Jr. et al (6,214,045) constitutes prior art and can be used in a rejection due to the earlier disclosure.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-2701. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

BS

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